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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,015	02/17/2005	Noboru Yamaji	Q86324	5025

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,015	YAMAJI ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2 and 4-12 is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/24/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending and claims 1, 2, and 4-12 have been examined on the merits.

Abstract

The abstract of the disclosure is objected to because the abstract should not refer to purported merits or speculative applications of the invention, i.e. '... effective for the prevention and treatment of disease and pathological conditions involving the degradation...' and the abstract should avoid use of phrases such as 'of the present invention' when describing the invention. Correction is required. See MPEP § 608.01(b).

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application PCT JP03/10460, filed August 19, 2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the

filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit

claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

Applicant's IDS, submitted June 24, 2005, has been considered. References submitted, but not in English, have been considered insofar as the supplied English abstract, and/or to the extent that they are discussed in the specification, and/or to the extent they are discussed in the IPER, submitted by Applicant February 17, 2005.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. Claim 3 depends from claim 1, yet incorporates reference to the compounds of claim 2. In order to obviate this objection, Applicant could amend the claim to depend from claim 2, e.g. "The agent according to claim [[1]] 2 ..."

Claims 2, 4 and 12 are objected to because of the following informalities:

Claim 2 recites, "a depsipeptide compound represented by the following formula (I), a depsipeptide compound represented by the following general formula (II), a depsipeptide compound represented by the following general formula (IIa)...and butyric acid:" Applicant is suggested to amend the claim by reordering the Markush group to place the recitation immediately preceding the chemical structures, e.g., "The agent ...butyric acid, a depsipeptide

compound represented by the following formula (I), a depsipeptide compound represented by the following general formula (II), and a depsipeptide compound represented by the following general formula (IIa):".

Claim 4 recites, "to a method described in...", which is improper because a claim should not refer to a secondary document, e.g. *Yoshida*. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR § 1.57(f). (*see also* MPEP 608.01(p)).

Claim 12 recites, "administrating", which is grammatically incorrect and should be "administering".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for agents (compounds) that treat and methods of treating arthrosteitis, rheumatic arthritis, osteoarthritis and inhibiting articular cartilage extracellular matrix degradation, does not reasonably provide enablement for agents that prevent arthrosteitis, rheumatic arthritis, osteoarthritis and articular cartilage extracellular matrix degradation or methods of preventing or treating a "disease caused by articular cartilage extracellular matrix degradation." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. § 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to agents that treat or prevent arthrosteitis, rheumatic arthritis, osteoarthritis and articular cartilage extracellular matrix degradation and methods of preventing or treating a "disease caused by articular cartilage extracellular matrix degradation". Thus, the claims taken together with the specification imply HDACi inihibitors could treat or prevent a myriad of diseases or conditions associated with or preceded by articular cartilage extracellular matrix degradation.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Rheumatoid arthritis (RA) is unpreventable, "because the exact cause of the disease is unknown" ("Rheumatoid Arthritis: Prevention"- <http://www.webmd.com/hw/rheumatoid_arthritis/aa19581.asp>, 1 page, updated 8/7/2004, accessed 3/21/06).

The causes of osteoarthritis (OA) are unknown (Page 2, "Osteoarthritis" NIH Publication 02-4617. July 2002, 34 pages) and there are no known prevention modalities (page 30).

Various HDACi are known in the art to treat, e.g. rheumatoid arthritis, as stated in the instant specification (*see* pages 6-7).

Pulmonary fibrosis is recognized in the art as being a disease caused by RA. RA involves ECM degradation, or is caused by ECM, and thus, one could reasonably conclude that pulmonary fibrosis is caused by the ECM degradation of RA.

The art teaches that, "There is no evidence that any medications can help [idiopathic pulmonary fibrosis]" (page 2, G. Schiffman. "Pulmonary Fibrosis"- MedicineNet.

<http://www.medicinenet.com/pulmonary_fibrosis/article.htm>, 2 pages, accessed 3/22/06, revised 9/27/05).

Furthermore, arthrosteitis is a generic term of the art for 'inflammation of the joint.' Additionally, the art recognizes that ECM degradation is involved with RA and OA.

Because RA and OA are unpreventable, RA, OA and generically, arthrosteitis, prevention as provided by the art is highly unpredictable, as it has yet to be accomplished. Furthermore, the art is highly unpredictable to treat or prevent all unknown diseases that are 'caused by' ECM degradation, particularly since, e.g. pulmonary fibrosis, is an untreatable condition.

(5) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided examples of *in vitro* inhibition of PG cartilage degradation using an asserted 'conventional' model for evaluating compounds which may inhibit ECM degradation in articular cartilage and in the mouse model of athrosteitis.

The specification provides that arthrosteitis, OA and RA are, "diseases in which damage and degeneration of articular cartilage is a main lesion." (page 7).

Additionally, Applicant admits that, "there has been no report which indicates that an HDAC inhibits degradation and degeneration of articular cartilage [ECM] and is effective for the prevention and treatment of joint diseases involving degradation and degeneration of the articular cartilage [ECM]." (page 6).

The specification does not provide any examples, working or prophetic, to prevent any disease 'caused by' ECM degradation, e.g. pulmonary fibrosis, beyond OA and RA, which are also recognized as involving degradation, nor does the specification provide any limiting

definitions as to what diseases are 'caused by' ECM degradation, indicating that joint diseases *involve* degradation.

(6) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above and the high unpredictability and the inability to prevent RA or OA, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make agents (compounds) that prevent arthrosteitis, rheumatic arthritis, osteoarthritis and articular cartilage extracellular matrix degradation or practice the methods of preventing or treating a "disease caused by articular cartilage extracellular matrix degradation," except for treating OA, RA and arthrosteitis and inhibiting articular cartilage ECM degradation.

Applicant have reasonably demonstrated/disclosed that the claimed compound is useful as a therapeutic agent for treating OA, RA and arthrosteitis and inhibiting articular cartilage ECM degradation. However, the claims also encompass using the claimed compound to prevent OA, RA and arthrosteitis and diseases caused by articular cartilage ECM degradation which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) – including preventing such disorders as RA, OA, pulmonary fibrosis, which are clearly not recognized in the medical art as being totally preventable conditions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "CHAP" which is vague and indefinite because CHAP "cyclic hydroxamic acid-containing peptide " does not describe a single compound, but rather a class of compounds, and thus it is unclear whether Applicant is intending to claim a single CHAP, or the collection of CHAP. For example, FURUMAI (R. Furumai, et al. Proc. Natl. Acad. Sci. USA. (2001) 98(1), pages 87-92) teaches CHAPs 1, 13, 15, 30, 49, 53 and 56 (Table 1, page 89) and CHAPs 17 and 18 (Figure 2, page 89).

Claim 4 recites, "to a method described in...", which is vague and indefinite. The claim recites reference to a separate document, however the claim does not recite exactly what method step(s) is/are required to test the compound for the requisite activity. Additionally, it is unclear which method of *Yoshida* is required for testing, as *Yoshida* teaches several methods which could be used to test IC_{50} values.

Furthermore, the MPEP states that where possible, claims are to be complete in themselves and that "Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). MPEP § 608.01(m).

Claim 11 provides for the use of 'a histone deacetylase-inhibitor', but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 recites, '...caused by articular cartilage extracellular matrix degradation..." which is unclear and indefinite because the specification does not set forth the metes and bounds of diseases 'caused by'. The specification provides non-limiting definitions of what diseases are 'caused by'- RA, OA, arthrosteitis, "and the like" (e.g. paragraph spanning page 10-11; *Industrial Applicability*, page 23). Furthermore, the art and specification provide that joint diseases involve degradation, but are not *per se* caused by it.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by KAMMER (WO 02/055017 A2; PTO-1449 June 24, 2005)

The instant claims are generally drawn to 'an agent' comprising a histone deacetylase inhibitor (HDACi) and a method of treating or preventing a disease caused by articular cartilage extracellular matrix degradation via administration of an HDACi.

Kammer teaches a method of treating rheumatoid arthritis (RA) with a histone hyperacetylating agent (claim 10). The contemplated hyperacetylating agents used in the method are HDACi (claim 2), including Trichostatin A, SAHA, Trapoxin A, FR901228, Apicidin, MS-27-275 (a.k.a. MS-275), hydroxamic acid, phenylbutyrate, and Depudecin (Claims 3-9; *see also Specification pages 6-8*).

Kammer further teaches pharmaceutical compositions are be formulated for various routes of administration, e.g. oral, iv, parenteral, topical, using standard techniques (page 10, lines 3-9).

Applicant is reminded that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less.

Furthermore, Applicant admits in the specification that Kammer, "describes that an HDAC inhibitor can be used for the treatment of autoimmune diseases including rheumatic arthritis" (*Specification*, paragraph spanning page 6 and 7).

Claims 1, 2, 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by GEERTS (US Patent 5,993,845).

The instant claims are presented *supra*. Geerts teaches a method of treating fibrosis comprising administration of an HDACi in a pharmaceutical composition (claim 6) where the HDACi is trichostatin A (claim 9) or sodium butyrate (claim 10). Geerts teaches that other known HDACi are trapoxin, apicidin A, HC-toxin and chlamydocin (column 2, lines 5-23).

As stated above, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have

the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits in the specification that the compounds are known in the art (*pages 2-6*).

Claims 1, 2, 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by SKOV (US Patent 6,403,555 B1).

The instant claims are presented *supra*. Skov teaches FR901228, which is also known as FK228, formulated as a pharmaceutical composition (column 2, lines 20-22) and administered to mice in 10% DMSO in saline (column 27, Tables 2A and 2B). Administration of the compound would necessarily prevent diseases caused by articular cartilage extracellular matrix degradation.

As stated above, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less.

Furthermore, Applicant admits in the specification that the compounds are known in the art (*page 4*).

Claims 1, 2, 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by BAIR (WO 02/22577 A2; PTO 1449 June 24, 2005).

The instant claims are presented *supra*. Bair teaches NVP-LAQ824 (*see Example P2*, page 27; compound 192), as a pharmaceutical compositions (claim 35) and administered to a mammal to treat a proliferative disorder (claim 38).

As stated above, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have

the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits in the specification that NVP-LAQ824 is known in the art (*page 4*).

Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by NAKA-JIMA (WO 02/06307 A1; PTO 1449 June 24, 2005).

The instant claims are presented *supra*. Naka-Jima teaches FR135313 (a.k.a. FK228(reduced)) (page 7, structure drawn top of page; Abstract R^1 and R^2 each H) and that the compounds of the invention are useable in preventing and treating diseases. Applicant refers to this compound as 'formula (I)'.

As stated above, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits in the specification that FK228(reduced) (FR135313) is known in the art (*page 4*).

Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by NOBUAKI (JP 2001-348340 A; PTO 1449 June 24, 2005).

Nobuaki teaches a depsipeptide which is instantly claimed as formula (II) (*see* English Abstract). The compounds are used for treating autoimmune diseases (Abstract).

As stated above, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have

the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits that the compound is known in the art (*page 4*).

Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by KINYA (JP 2001-354694 A; PTO 1449 June 24, 2005).

Kinya teaches a depsipeptide which is instantly claimed as formula (IIa) as admitted by Applicant (Specification, *page 4*).

As stated above, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits that the compound is known in the art (*page 4*).

Claims 1, 2, 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by GÖTTLICHER (Göttlicher; PTO 1449 June 24, 2005).

Göttlicher teaches Valproic acid as an HCADi (*Title*) and that, "valproic acid has been used in the treatment of epilepsy for almost 30 years" (page 6974, *Discussion*).

In the instant case, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits that the compound is known in the art (*page 4*).

Claims 1, 2, 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by RIVA (L. Riva, et al. Clin. Cancer Res. (2000) 6, pages 994-997).

Riva teaches CI-994 and that administered to Rhesus monkeys (e.g. *Discussion*, page 996).

In the instant case, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by FURUMAI, *supra.*

Furumai teaches various CHAPs (e.g. Table 1, page 89).

In the instant case, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits that the compound is known in the art (*page 4*).

Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by CUTTS (S.M. Cutts, et al. Cancer Res. (2001) 61, pages 8194-8202).

Cutts teaches AN-9, pivaloyloxymethy butyrate (Abstract, throughout) formulated in lipid emulsion (PIVANEX®) is in Phase II clinical trials for patients with non-small cell lung carcinoma and hepatoma patients (page 8194).

In the instant case, the prior art compounds would necessarily function as instantly claimed, e.g. as a therapeutic or preventative agent for the various conditions, and would necessarily have the requisite IC_{50} value of 100 μM or less. Additionally, administration of the compound would necessarily 'prevent' the conditions as asserted.

Furthermore, Applicant admits that the compound is known in the art (*page 4*).

Conclusion

NO CLAIMS ARE ALLOWED.

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Art Unit 1654

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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